

FF
WO 03/086509 A1

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
23 October 2003 (23.10.2003)

PCT

(10) International Publication Number
WO 03/086509 A1

(51) International Patent Classification⁷: A61M 5/168,
1/28

(21) International Application Number: PCT/US03/11090

(22) International Filing Date: 10 April 2003 (10.04.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/371,894 11 April 2002 (11.04.2002) US

(71) Applicant: DEKA PRODUCTS LIMITED PARTNERSHIP [US/US]; 340 Commercial Street, Manchester, NH 03102 (US).

(72) Inventors: DISTLER, Carl, Ray; 5001 Sunset Bluff, Huntsville, AL 35803 (US). DISTLER, Gregory, Lee;

9503 Hemlock Drive, Huntsville, AL 35803 (US). DEMERS, Jason, A.; 387 North Bay Street, Manchester, NH 03104 (US). SPENCER, Geoffrey, P.; 40 Fogg Court, Manchester, NH 03104 (US). BRYANT, Robert; 222 Blucher Street, Manchester, NH 03102 (US).

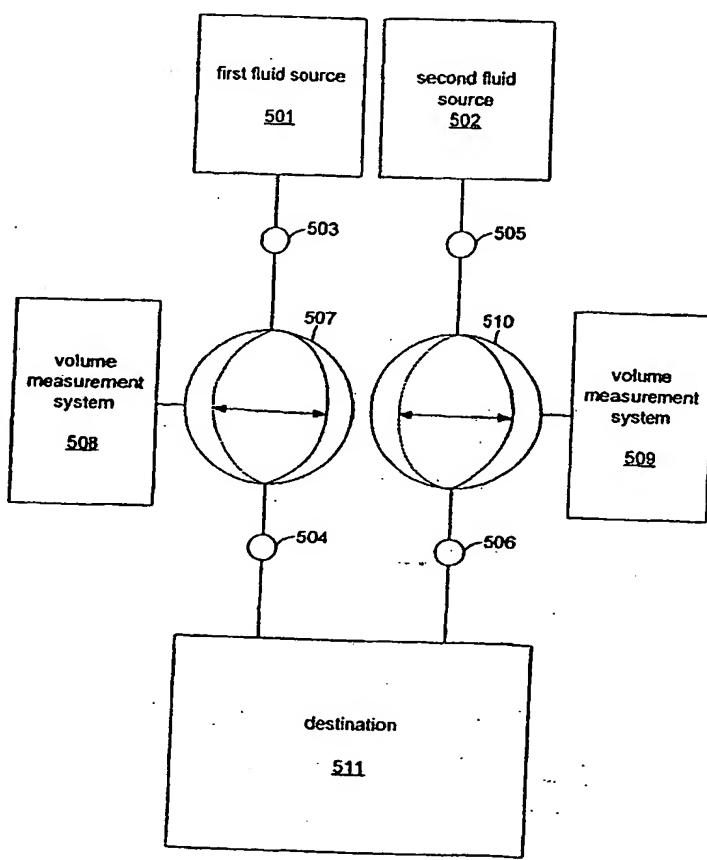
(74) Agents: SUNSTEIN, Bruce, D. et al.; Bromberg & Sunstein LLP, 125 Summer Street, Boston, MA 02110-1618 (US).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),

[Continued on next page]

(54) Title: SYSTEM AND METHOD FOR DELIVERING A TARGET VOLUME OF FLUID



(57) Abstract: A method for delivering a target volume of fluid to a destination is provided. The method includes delivering a first volume of fluid to the destination in increments each having approximately a first incremental volume, the first volume of fluid being less than the target volume and delivering a second volume of fluid to the destination in increments each having approximately a second incremental volume, the second incremental volume being less than the first incremental volume, such that the sum of the first volume and the second volume is approximately equal to the target volume.



Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

Published:

— with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

System and Method for Delivering a Target Volume of Fluid

Technical Field and Background Art

The present invention relates to fluid delivery systems, and in particular to
5 systems and methods for accurately delivering a target volume of fluid to a destination.

Such systems regulate the rate of flow of fluid through a line. Some examples of
fluid delivery systems are peritoneal dialysis machines and intravenous fluid delivery
systems. These systems may include a permanent housing which does not come into
direct contact with the transporting fluid and into which a fluid-exposed disposable
10 cassette is placed. The disposable cassette includes flexible membranes, or other
structures that respond to pressure and that separate the permanent components from the
fluid being delivered. Examples of such fluid delivery systems and their sub-components
(e.g., pressure conduction chambers, flow measurement systems and valves) are disclosed
in U.S. Patent Numbers 4,778,451, 4,826,482, 4,976,162, 5,088,515, 5,178,182 issued to
15 Kamen, U.S. Patent Number 5,989,423 issued to Kamen et al. and U.S. Patent No.
6,503,062 issued to Gray et al. These patents are all hereby incorporated herein by
reference.

One problem with respect to fluid delivery systems, such as in peritoneal dialysis,
arises when treating subjects with low fill volume capacities, such as a child. For
20 example, in peritoneal dialysis systems, a fill volume of 1000 mL or less generally
indicates a low fill volume while fill volumes of greater than 1000 mL are typical for an
average adult's fill volume. Thus, a single fluid delivery system may not be appropriate
for treating both an average adult and a child.

Another problem arises with respect to fluid delivery systems when two or more
25 fluids from two or more sources must be delivered to a subject or patient simultaneously
and in a particular ratio. It is difficult to maintain a consistent ratio of the different fluids
for simultaneous delivery to the subject because each source may deliver its solution to
the system at different rates and/or in different volumes. Consequently, it is difficult to
maintain a consistent ratio of the different fluids in the fluid delivery system at any one
30 time.

Summary of the Invention

In a first embodiment of the invention, a method for delivering a target volume of fluid to a destination includes delivering a first volume of fluid to the destination in increments each having approximately a first incremental volume, the first volume of fluid being less than the target volume. A second volume of fluid is then delivered to the destination in increments each having approximately a second incremental volume. The second incremental volume is less than the first incremental volume, and the sum of the first volume and the second volume is approximately equal to the target volume.

Delivering the first and second volumes of fluid to a destination may include delivering the first and second volumes of fluid parenterally to a human subject. Similarly, delivering the first and second volumes of fluid to a destination may include delivering the first and second volumes of fluid to a fluid reservoir and/or delivering the first and second volumes of fluid to a container. Such a container may be a heating bag, such as may be used in conjunction with a peritoneal dialysis system, and/or a pump chamber. In accordance with a related embodiment, the first volume may be approximately equal to the target volume minus a finish volume and the second incremental volume may be less than the finish volume. In a related embodiment, the second incremental volume may be less than one third the finish volume.

In accordance with another embodiment of the invention, a system for delivering a target volume of fluid to a destination includes a fluid control module for delivering a first volume of fluid to the destination in increments each having approximately a first incremental volume, the first volume of fluid being less than the target volume. The fluid control module also delivers a second volume of fluid to the destination in increments each having approximately a second incremental volume, the second incremental volume being less than the first incremental volume. The sum of the first volume and the second volume is approximately equal to the target volume. The system also includes a valve arrangement for controlling fluid communication to the destination and a controller for determining the volume of fluid delivered to the destination and for controlling the valve arrangement and the fluid control module. The fluid control module may deliver the first and second volumes of fluid to a human subject and the first and second volumes of fluid may be delivered parenterally. Similarly, the fluid control module may deliver the first and second volumes of fluid to a fluid reservoir and/or a container such as a heating bag and/or a pump chamber.

In accordance with related embodiments, the first volume may be approximately

equal to the target volume minus a finish volume and the second incremental volume may be less than the finish volume. For example, the second incremental volume may be less than one third the finish volume.

In accordance with a further embodiment of the invention, a method for
5 simultaneously delivering a target volume of fluid from two sources in a desired ratio to a common destination includes delivering a first volume of fluid from a first source and a second volume of fluid from a second source to the destination in increments each having approximately a first incremental volume, the first incremental volume of fluid being substantially less than the target volume. After delivery of a first incremental volume of
10 fluid from the first source and the second source, the volume of fluid delivered to the destination from the first source and the volume of fluid delivered to the destination from the second source is measured. Delivery of the first volume of fluid to the destination is suspended when the first volume exceeds the second volume by a fraction, which may be a predetermined fraction, of the first incremental volume. A first incremental volume of
15 fluid from the second source is delivered to the destination, and delivery of the first volume of fluid to the destination is resumed.

In accordance with related embodiments, the first incremental volume of fluid may be less than one quarter of the target volume. In accordance with further related embodiments, the desired ration may be 1:1 and the predetermined fraction may be one half. Delivering the first and second volumes of fluid to a destination may include delivering the first and second volumes of fluid parenterally to a human subject. Similarly, delivering the first volume and second volumes of fluid to a destination may include delivering the first and second volumes of fluid to a fluid reservoir and/or container, and such a container may be a heating bag and/or a pump chamber.

25 In accordance with other related embodiments, the method may include determining that approximately the target volume of fluid has been delivered to the destination and measuring the volume of fluid delivered to the destination from the first source and the volume of fluid delivered to the destination from the second source. A third volume of fluid from the source that has delivered a smaller volume of fluid to the
30 destination may then be delivered in increments each having approximately a second incremental volume, the second incremental volume being less than the first incremental volume, such that the volume of fluid delivered to the destination from the first source and the volume of fluid delivered from the second source are in approximately the desired ratio. The sum of the first volume and the second volume may be approximately equal to

the target volume minus a finish volume, and the second incremental volume may be less than the finish volume. In one related embodiment, the second incremental volume is less than one third the finish volume.

In accordance with another embodiment of the invention, a system for
5 simultaneously delivering a target volume of fluid from two sources in a desired ratio to a common destination includes a first fluid source, a second fluid source, and a fluid control module. The fluid control module delivers a first volume of fluid from the first fluid source and a second volume of fluid from the second fluid source to the destination in increments each having approximately a first incremental volume, the first incremental volume being substantially less than the target volume. The fluid control module also measures the volume of fluid delivered to the destination from the first source and the volume of fluid delivered to the destination from the second source, suspends delivery of the first volume of fluid to the destination when the first volume exceeds the second volume by a fraction, which may be a predetermined fraction, of the first incremental
10 volume, and resumes delivery of the first volume of fluid to the destination. The system also includes a valve arrangement for controlling fluid communication between the destination and first and second fluid sources and a controller for determining the first and second volumes of fluid, the first incremental volume of fluid, and for controlling the valve arrangement and the fluid control module.
15

20 In accordance with related embodiments, the first incremental volume may be less than one quarter of the target volume. Additionally, the desired ratio may be 1:1 and the predetermined fraction may be approximately one half. In accordance with yet further related embodiments, the fluid control module may deliver the first and second volumes of fluid to a human subject, and the fluid control module may deliver the first and second volumes of fluid parenterally. Similarly, the fluid control module may deliver the first and second volumes of fluid to a fluid reservoir and/or to a container. Such a container
25 may be a heating bag and/or a pump chamber. The controller may also determine that approximately the target volume minus a finish volume of fluid has been delivered to the destination. Further, the fluid control module may measure the volume of fluid delivered to the destination from the first source and the volume of fluid delivered to the destination from the second source and deliver a third volume of fluid from the source that has delivered a smaller volume of fluid to the destination. The third volume of fluid may be delivered in increments each having approximately a second incremental volume. The second incremental volume may be less than the first incremental volume, such that the
30

volume of fluid delivered to the destination from the first source and the volume of fluid delivered from the second source are in approximately the desired ratio. Further, the sum of the first and the second volumes may be approximately equal to the target volume minus a finish volume and the second incremental volume may be less than the finish 5 volume. For example, the second incremental volume may be less than one third the finish volume.

In accordance with a further embodiment of the invention, a system for delivering a target volume of fluid to a destination includes fluid delivery means for delivering a first volume of fluid to the destination in one or more first incremental volumes, the first 10 volume of fluid being less than the target volume, and delivering a second volume of fluid to the destination in one or more second incremental volumes, the second incremental volume being less than the first incremental volume. The system also includes measuring means for measuring the volume of fluid delivered to the destination and control means for controlling the fluid delivery means.

15 In accordance with another embodiment of the invention, a system for simultaneously delivering a target volume of fluid from two sources in a desired ratio to a common destination includes a first fluid source and a second fluid source. Fluid delivery means delivers a first volume of fluid from the first fluid source and a second volume of fluid from the second fluid source to the destination in one or more first 20 incremental volumes, the first incremental volume being substantially less than the target volume. Measuring means measures the volume of fluid delivered to the destination from the first source and the volume of fluid delivered to the destination from the second source. Control means suspends delivery of the first volume of fluid to the destination when the first volume exceeds the desired ratio with respect to the second volume by a fraction, which may be a predetermined fraction, of the first incremental volume and then resumes delivery of the first volume of fluid to the destination.

25 In accordance with a further embodiment of the invention, a system for simultaneously delivering a target volume of fluid from two sources in a desired ratio to a common destination includes a first fluid source and a second fluid source. The system also includes fluid delivery means for delivering a first volume of fluid from the first fluid source and a second volume of fluid from the second fluid source to the destination in one or more first incremental volumes, the first incremental volume being substantially less than the target volume, and measuring means for measuring the volume of fluid 30 delivered to the destination from the first source and the volume of fluid delivered to the

destination from the second source. The control means suspends delivery of the first volume of fluid to the destination when the first volume exceeds the second volume by a fraction, which may be a predetermined fraction, of the first incremental volume and resumes delivery of the first volume of fluid to the destination. In accordance with related embodiments, the desired ratio may be 1:1 and the predetermined fraction may be approximately one half.

Brief Description of the Drawings

The foregoing features of the invention will be more readily understood by reference to the following detailed description, taken with reference to the accompanying drawings, in which:

Fig. 1 is a perspective view of an automated fluid delivery system that may be used in conjunction with the present invention;

Fig. 2 is a flow chart illustrating a method for delivering a target volume of fluid to a destination in accordance with an embodiment of the invention;

Fig. 3 is a flow chart illustrating a method for simultaneously delivering a target volume of fluid from two sources in a desired ratio to a common destination in accordance with another embodiment of the invention;

Fig. 4 is a flow chart illustrating a method for simultaneously delivering a target volume of fluid from two sources in a desired ratio to a common destination in accordance with yet another embodiment of the invention; and

Fig. 5 is a block diagram illustrating one example of a system for employing the methods of Figs. 3 and 4.

Detailed Description of Specific Embodiments

Fig. 1 is a perspective view of an automated fluid management system that may be used in conjunction with the present invention. The system 100 includes a liquid supply and delivery set 102, a fluid control module 104 that interacts with the delivery set 102 to pump liquid through it, and a controller 106 that governs the interaction to perform a selected procedure. In the depicted embodiment, the fluid control module and controller are located within a common housing 182.

The fluid control module 104 utilizes a pneumatic pumping action to emulate gravity flow, regardless of the position of the source solution bags 184. The pumping

action may be the result of pressurizing one or more fluid chambers through use of a control gas or liquid, or other methods known in the art, such as pumps, pistons, piezo-electric mechanisms, pressurized reservoirs, valves, clamps and vents. As noted above, these pressurizing devices are explained in greater detail in the patents referenced above and incorporated herein by reference.

The controller 106 carries out process control and monitoring functions for the fluid control module 104. The controller includes a user interface 167 with a display screen 137 and control pad. The interface 167 presents menus, sub-menus and status information to the user during a therapy session. The interface 167 also allows the user to enter and edit therapy parameters, and to issue therapy commands. In one embodiment, the user interface 167 receives characters from a keypad, displays text to the display screen 137 and sounds an alarm when appropriate. The control pad may include a "Go" key 135, which when pressed causes the interface 167 to display a main menu on the display screen 137 for initiating a therapy session, and a "Stop" key 139 which when pressed causes a therapy session to cease. The interface 167 may also include keys 133 for traversing through the information and menus displayed on the display screen 137 and an "Enter" key 134 for causing data to be input to the system or for selecting an entry from the menus.

In the illustrated embodiment, the controller 106 comprises a central processing unit. The central processing unit may employ conventional real time multi-tasking to allocate tasks. The central processing unit may itself be programmable or alternatively, it may run under the direction of a software, middle-ware or hardware program external to the system.

In use, for example as a peritoneal dialysis system, the user connects the set 102 to his/her indwelling peritoneal catheter 108. The user also connects the set 102 to individual bags 184 containing peritoneal dialysis solution for infusion. The set 102 also connects to a heating bag 180 in which the dialysis solution is heated to a desired temperature. In accordance with an embodiment of the invention described in more detail below, two or more fluids from different sources may be simultaneously pumped to the heating bag in a desired ratio.

The controller 106 paces the fluid control module 104 through a prescribed series of fill, dwell, and drain phases typical of an automated peritoneal dialysis procedure. During the fill phase, the fluid control module 104 infuses the heated solution through the set 102 and into the patient's peritoneal cavity. Following the dwell phase, the fluid

control module 104 institutes a drain phase, during which the fluid control module 104 discharges spent dialysis solution from the patient's peritoneal cavity through the set into a nearby drain.

The delivery set 102 includes a cassette (not visible) which mounts inside a holder 5 in the fluid control module 104. The cassette serves in association with the fluid control module 104 and the controller to direct liquid flow among multiple fluid sources and destinations that an automatic peritoneal dialysis procedure requires. The cassette forms an array of interior cavities in the shapes of wells and channels. The interior cavities create one or more pump chambers and one or more paths to convey fluid. The interior 10 cavities also create one or more valve stations to interconnect the fluid paths with the pump chambers and with each other. The number and arrangement of pump chambers, liquid paths and valve stations can vary. Such a cassette is described in U.S. Patent No. 5,989,423 and U.S. Patent No. 5,178,182 both of which, as noted above, are incorporated herein by reference.

In order to accommodate patients with small abdominal cavities, a new process 15 and system is presented that limits the available fill volume. A clinician will be able to select a "low fill mode" from among the modes available on the fluid delivery system. For example, when the low fill mode is on, the fill volumes available will be limited to a range of 60-1000 mL.

Since the fill volumes for the low-fill mode may be as small as 60 mL, it is 20 necessary to achieve a high level of targeting accuracy for these applications. An acceptable range of accuracy may be, for example, +5 mL/-10 mL. It may also be desirable that conforming to this accuracy specification does not take substantially longer than a standard fill.

The targeting accuracy is improved by executing a more intermittent fill during 25 the last phase, in which the incoming flow is stopped one or more times to perform a volume measurement and assess progress. The nominal operation of this fill routine does not result in fills that consistently stop at the low end of the tolerance; instead the nominal operation should fill to the mid-point of the tolerance range. This fill routine especially 30 improves performance for low-fill applications.

Fig. 2 illustrates a method (i.e., a fill routine) for delivering a target volume of fluid to a destination in accordance with one embodiment of the invention. Such a destination may be a human subject, the heating bag 180, a reservoir, a fluid container or pump chamber as illustrated with respect to Fig. 5. The fluid may further be delivered to

the human subject parenterally. The method includes delivering 201 a first volume of fluid to the destination in increments each having approximately a first incremental volume. The first volume of fluid is less than the target volume by an amount at least as large as the first incremental volume. For example, if the target volume is 500 mL, the 5 first incremental volume may be 10 to 50 mL. A second volume of fluid is then delivered 202 to the destination in increments each having approximately a second incremental volume. The second incremental volume is less than the first incremental volume, and the sum of the first volume and the second volume is approximately equal to the target volume. For example, if the first incremental volume is 15 mL, then the second 10 incremental volume may be 1 to 3 mL. Note that a plurality of first incremental volumes may be delivered before delivering the second volume. Thus, to achieve a target volume of 500 mL, the first volume may be approximately 485 mL, delivered in thirty or more first incremental volumes of approximately 15 mL each, before the second volume of fluid is delivered in the second incremental volumes of approximately 1 to 3 mL each. 15 Thus, the first volume may approximately equal the target volume minus a finish volume (i.e., the second volumes) and the second incremental volume may be less than the finish volume. For example, the second incremental volume may be one third the finish volume

Fig. 3 is a flow chart illustrating a method for simultaneously delivering a target volume of fluid from two sources in a desired ration, in this case in a 1:1 ratio, to a 20 common destination. Again, such a destination may be a human subject, the heating bag 180, a reservoir, a fluid container or pump chamber. Further, the fluid may be delivered to a human subject parenterally. In a first step, a first volume of fluid from a first source and a second volume of fluid from second source is delivered 301 to the destination in increments each having approximately a first incremental volume. The first volume may be measured in one or more of the pump chambers discussed above in connection with the fluid delivery system of Fig. 1 and in connection with the system Fig. 5. In one embodiment, for example, the volume measurement systems of U.S. Patent Nos. 4,976,162 and 4,826,482 (incorporated herein above) are employed. The first incremental volume of fluid is substantially less than the target volume. In one 25 embodiment, the first incremental volume is less than one quarter of the target volume. However, the first incremental volume may be less than the target volume by any desired fraction, such as one eighth, one third, one half, two thirds, etc.

After delivery of a first incremental volume of fluid from each of the first source and the second source, the volume of fluid delivered to the destination from the first

source and the volume of fluid delivered to the destination from the second source is measured 302. Such delivery may occur simultaneously and such measurements may be performed by the controller 106 by using pressure transducers contained in the fluid control module 104 or other fluid volume measuring apparatuses. Delivery of the first 5 volume of fluid to the destination is suspended 303 when the first volume exceeds the second volume by a fraction, which may be a predetermined fraction, of the first incremental volume. For example, delivery of the first volume of fluid to the destination may be suspended when the first volume exceeds the second volume by approximately one half of the first incremental volume in order to attain a 1:1 one ratio. A first 10 incremental volume of fluid is then delivered 304 to the destination from the second source, and delivery of the first volume of fluid to the destination is resumed 305. It will be appreciated that this process may be adapted for a desired ratio other than one-to-one. In such a case, the fluids from different sources may be delivered by incremental volumes that are the same or that are different from each other. It will also be appreciated that this 15 process may be adapted for use with fluids from more than two different sources.

Fig. 4 is a flow chart illustrating a method for simultaneously delivering a target volume of fluid from two sources in a desired (such as a one-to-one) ratio to a common destination in accordance with yet another embodiment of the invention. The procedure begins in a manner similar to that shown with respect to the embodiment of Fig. 3. That 20 is, a first volume of fluid from a first source and a second volume of fluid from second source is delivered 401 to the destination in increments each having approximately a first incremental volume. The first incremental volume of fluid is less than the target volume. In this case the first incremental volume is less than one quarter of the target volume. However, as noted above the first incremental volume may be less than the target volume 25 by any desired ratio. After delivery of a first incremental volume of fluid from each of the first source and the second source, the volume of fluid delivered to the destination from the first source and the volume of fluid delivered to the destination from the second source is measured 402. Again, such measurements may be performed by the controller 106 by using pressure transducers contained in the fluid control module 104 or other fluid 30 volume measuring means. Delivery of the first volume of fluid to the destination is suspended 403 when the first volume exceeds the second volume by a fraction, which may be a predetermined fraction, of the first incremental volume, in this case by one half the first incremental volume. A first incremental volume of fluid is then delivered 404 to

the destination from the second source, and delivery of the first volume of fluid to the destination is resumed 405.

In order to assure that the target volume is delivered in the desired ratio, a determination is made 406 when approximately the target volume of fluid has been 5 delivered to the destination. The volume of fluid delivered to the destination from the first source and the volume of fluid delivered to the destination from the second source are then measured 407. Following this measurement, a third volume of fluid from the source that has delivered a smaller volume of fluid to the destination is delivered 408 in increments each having approximately a second incremental volume. The second 10 incremental volume is less than the first incremental volume. As a result of delivering the third volume of fluid, the sum of the volume of fluid delivered to the destination from the first source and the volume of fluid delivered from the second source are in approximately the desired ratio, in this case a one to one ratio. The first volume and the second volume may each be approximately equal to the target volume minus a finish 15 volume. Similarly, the second incremental volume may be less than the finish volume by any desired fraction. For example, in this embodiment, the second incremental volume may be one third the finish volume:

A system similar to the one described with respect to Fig. 1 may incorporate the processes described above. In this case the fluid control module 104 or other fluid 20 delivery means such as those disclosed in the patents incorporated above, delivers a first volume of fluid to the destination in increments each having approximately a first incremental volume, the first volume of fluid being less than the target volume. The fluid control module 104 will also deliver a second volume of fluid to the destination in increments each having approximately a second incremental volume. Here again, the 25 second incremental volume is less than the first incremental volume, such that the sum of the first volume and the second volume is approximately equal to the target volume. The system additionally includes a valve arrangement, shown generally at 105 for controlling fluid communication between the fluid source or sources and the destination as well as a controller, such as controller 106 or other control means such as a microprocessor or 30 computer. The controller 106 determines the volume of fluid delivered to the destination and controls the valve arrangement 105 and the fluid control module 104. The controller 106 may also determine when approximately the target volume minus a finish volume of fluid has delivered to the destination. In addition, the fluid control module 104 may measure the volume of fluid delivered to the destination from the first source and the

volume of fluid delivered to the destination from the second source. The fluid control module 104 may then deliver a third volume of fluid from the source that has delivered a smaller volume of fluid to the destination in increments each having approximately a second incremental volume.

- 5 Fig. 5 is a block diagram illustrating an example of a system for employing the methods of Figs. 3 and 4 above. The system includes a first fluid source 501 and a second fluid source 502. The first fluid source 501 is in fluid communication with a first pump chamber 507 via valve 503 and the second fluid source 502 is in fluid communication with a second pump chamber 510 via valve 505. Pump chamber 507 is 10 also in communication with a volume measurement system 508 and pump chamber 510 is in communication with volume measurement system 509. Alternatively, each pump chamber 507 and 510 may be in communication with a common volume measurement system. Each of the pump chambers 501 and 502 may include flexible membranes as described in the above referenced and incorporated patents. Similarly, each of the 15 volume measurement systems 508 and 509 may include pressure transducers and positive and/or negative pressure reservoirs as are also described in the aforementioned incorporated patents. Each of the pump chambers 507 and 510 is in fluid communication with a destination 511 via valves 504 and 506 respectively. As noted above, the destination 511 may be a human subject, a reservoir, a container, such as a heating bag, or 20 another, perhaps larger, pump chamber.

In accordance with one embodiment, the goal is to separately track the volumes moved from each fluid source 501 and 502 and to ensure that the difference between the fluid delivered from each of the two fluid sources never varies by more than half the volume of a pump chamber. This is achieved by performing in-phase pumping such that 25 both pump chambers 507 and 510 fill and deliver in sync. For example, if each pump chamber holds 15 mL, and it is determined that one pump chamber, for example pump chamber 507, has delivered at least 7.5 mL more fluid to the destination 511 than the other pump chamber 510, then fluid delivery from pump chamber 507 will be suspended while pump chamber 510 performs a catch-up stroke. Such a determination is made by 30 measuring the fluid volumes of each pump chamber 507 and 510 for each pumping stroke via volume measurement systems 508 and 509 respectively. (It should be noted that while each pump chamber 507 and 510 may have a capacity of 15 mL, somewhat less than 15 mL of fluid may be delivered to and by each pump chamber during any single pumping stroke.)

When the target volume (the volume of fluid intended to be delivered to the destination) has been delivered to the destination **511**, the pump chamber, perhaps pump chamber **510**, that has delivered the most fluid to the destination **511** will stop pumping. The pump chamber which has delivered the least amount of fluid, in this case pump chamber **507**, will then switch to a "targeting mode" in which a maximum of 3 mL of fluid is delivered to the destination **511** per pump chamber stroke. This targeting mode insures that a 1:1 ratio (or other desired ratio) between fluid delivered to the destination **511** from the first fluid source **501** and fluid delivered to the destination **511** from the second fluid source **502** is achieved to within approximately plus 2 mL or minus 1 mL.

While the invention has been described in connection with specific embodiments thereof, it will be understood that it is capable of further modification. This application is intended to cover any variation, uses, or adaptations of the invention and including such departures from the present disclosure as come within known or customary practice in the art to which the invention pertains.

15 01062/D54WO 247459.1

What is claimed is:

1. A method for delivering a target volume of fluid to a destination, the method comprising:
 - delivering a first volume of fluid to the destination in increments each having approximately a first incremental volume, the first volume of fluid being less than the target volume; and
 - delivering a second volume of fluid to the destination in increments each having approximately a second incremental volume, the second incremental volume being less than the first incremental volume, such that the sum of the first volume and the second volume is approximately equal to the target volume.
2. A method according to claim 1, wherein delivering the first and second volumes of fluid to a destination includes delivering the first and second volumes of fluid parenterally to a human subject.
3. A method according to claim 1 wherein the first volume is approximately equal to the target volume minus a finish volume.
4. A method according to claim 3, wherein the second incremental volume is less than the finish volume.
5. A method according to claim 3, wherein the second incremental volume is less than one third the finish volume.
6. A method according to claim 1, wherein delivering the first volume and second volumes of fluid to a destination includes delivering the first and second volumes of fluid to a fluid reservoir.
7. A method according to claim 1, wherein delivering the first and second volumes of fluid to a destination includes delivering the first and second volumes of fluid to a container.
8. A method according to claim 7, wherein the container is a heating bag.
9. A method according to claim 7, wherein the container is a pump chamber.
10. A system for delivering a target volume of fluid to a destination comprising:
 - a fluid control module for delivering a first volume of fluid to the destination in increments each having approximately a first incremental volume, the first volume of fluid being less than the target volume, and delivering a second volume of fluid to the destination in increments each having approximately a second incremental volume, the second incremental volume being less than the first incremental volume, such that the

sum of the first volume and the second volume is approximately equal to the target volume;

a valve arrangement for controlling fluid communication to the destination; and
a controller for determining the volume of fluid delivered to the destination and

5 for controlling the valve arrangement and the fluid control module.

11. A system according to claim 10, wherein the fluid control module delivers the first and second volumes of fluid to a human subject.

12. A system according to claim 11, wherein the fluid control module delivers the first and second volumes of fluid parenterally.

10 13. A system according to claim 10, wherein the fluid control module delivers the first and second volumes of fluid to a fluid reservoir.

14. A system according to claim 10, wherein the fluid control module delivers the first and second volumes of fluid to a container.

15. A system according to claim 14, wherein the container is a heating bag.

16. A system according to claim 14, wherein the container is a pump chamber.

17. A system according to claim 10, wherein the first volume is approximately equal to the target volume minus a finish volume.

18. A system according to claim 17, wherein the second incremental volume is less than the finish volume.

20 19. A system according to claim 17, wherein the second incremental volume is less than one third the finish value.

20. A method for simultaneously delivering a target volume of fluid from two sources in a desired ratio to a common destination, the method comprising:

25 delivering a first volume of fluid from a first source and a second volume of fluid from a second source to the destination in increments each having approximately a first incremental volume, the first incremental volume of fluid being substantially less than the target volume;

after delivery of a first incremental volume of fluid from the first source and the second source, measuring the volume of fluid delivered to the destination from the first 30 source and the volume of fluid delivered to the destination from the second source;

suspending delivery of the first volume of fluid to the destination when the first volume exceeds the second volume by a predetermined fraction of the first incremental volume;

delivering a first incremental volume of fluid from the second source; and

resuming delivery of the first volume of fluid to the destination.

21. A method according to claim 20, wherein the first incremental value is less than one quarter of the target value.
22. A method according to claim 20, wherein the desired ration is 1:1.
- 5 23. A method according to claim 22, wherein the predetermined fraction is one half.
24. A method according to claim 20, wherein delivering the first and second volumes of fluid to a destination includes delivering the first and second volumes of fluid parenterally to a human subject.
- 10 25. A method according to claim 20, wherein delivering the first volume and second volumes of fluid to a destination includes delivering the first and second volumes of fluid to a fluid reservoir.
26. A method according to claim 20, wherein delivering the first and second volumes of fluid to a destination includes delivering the first and second volumes of fluid to container.
- 15 27. A method according to claim 26, wherein the container is a heating bag.
28. A method according to claim 26, wherein the container is a pump chamber.
29. A method according to claim 20, further comprising:
 - determining that approximately the target volume of fluid has been delivered to the destination;
 - measuring the volume of fluid delivered to the destination from the first source and the volume of fluid delivered to the destination from the second source; and
 - delivering a third volume of fluid from the source that has delivered a smaller volume of fluid to the destination in increments each having approximately a second incremental volume, the second incremental volume being less than the first incremental
- 20 25. A method according to claim 29, wherein the volume of fluid delivered to the destination from the first source and the volume of fluid delivered from the second source are in approximately the desired ratio.
30. A method according to claim 29, wherein the sum of the first volume and the second volume is approximately equal to the target volume minus a finish volume.
30. 31. A method according to claim 30, wherein the second incremental volume is less than the finish volume.
32. A method according to claim 30, wherein the second incremental volume is less than one third the finish volume.
33. A system for simultaneously delivering a target volume of fluid

from two sources in a desired ratio to a common destination, the system comprising:

a first fluid source;

a second fluid source;

a fluid control module for:

5 delivering a first volume of fluid from the first fluid source and a second volume of fluid from the second fluid source to the destination in increments each having approximately a first incremental volume, the first incremental volume being substantially less than the target volume,

measuring the volume of fluid delivered to the destination from the first source
10 and the volume of fluid delivered to the destination from the second source,

suspending delivery of the first volume of fluid to the destination when the first volume exceeds the second volume by a predetermined fraction of the first incremental volume, and

resuming delivery of the first volume of fluid to the destination;

15 a valve arrangement for controlling fluid communication between the destination and first and second fluid sources; and

a controller for determining the first and second volumes of fluid, the first incremental volume of fluid, and for controlling the valve arrangement and the fluid control module.

20 34. A system according to claim 33, wherein the first incremental volume is less than one quarter of the target volume.

35. A system according to claim 33, wherein the desired ratio is 1:1.

36. A system according to claim 35, wherein the predetermined fraction is approximately one half.

25 37. A system according to claim 33, wherein the fluid control module delivers the first and second volumes of fluid to a human subject.

38. A system according to claim 37, wherein the fluid control module delivers the first and second volumes of fluid parenterally.

39. A system according to claim 33, wherein the fluid control module delivers the first and second volumes of fluid to a fluid reservoir.

40. A system according to claim 33, wherein the fluid control module delivers the first and second volumes of fluid to a container.

41. A system according to claim 40, wherein the container is a heating bag.

42. A system according to claim 40, wherein the container is a pump chamber.

43. A system according to claim 33, wherein the controller further determines that approximately the target volume minus a finish volume of fluid has been delivered to the destination; and

the fluid control module further:

5 measures the volume of fluid delivered to the destination from the first source and the volume of fluid delivered to the destination from the second source; and

delivers a third volume of fluid from the source that has delivered a smaller volume of fluid to the destination in increments each having approximately a second incremental volume, wherein the second incremental volume is less than the first

10 incremental volume, such that the volume of fluid delivered to the destination from the first source and the volume of fluid delivered from the second source are in approximately the desired ratio.

44. A system according to claim 43, wherein the sum of the first volume and the second volume is approximately equal to the target volume minus a finish volume.

15 45. A system according to claim 44, wherein the second incremental volume is less than the finish volume.

46. A system according to claim 44, wherein the second incremental volume is less than one third the finish volume.

47. A system for delivering a target volume of fluid to a destination
20 comprising:

fluid delivery means for delivering a first volume of fluid to the destination in one or more first incremental volumes, the first volume of fluid being less than the target volume, and delivering a second volume of fluid to the destination in one or more second incremental volumes, the second incremental volume being less than the first incremental volume;

measuring means for measuring the volume of fluid delivered to the destination; and

control means for controlling the fluid delivery means.

48. A system for simultaneously delivering a target volume of fluid
30 from two sources in a desired ratio to a common destination, the method comprising:

a first fluid source;

a second fluid source;

fluid delivery means for delivering a first volume of fluid from the first fluid source and a second volume of fluid from the second fluid source to the destination in one

or more first incremental volumes, the first incremental volume being substantially less than the target volume;

measuring means for measuring the volume of fluid delivered to the destination from the first source and the volume of fluid delivered to the destination from the second source; and

control means for suspending delivery of the first volume of fluid to the destination when the first volume exceeds the desired ratio with respect to the second volume by a fraction of the first incremental volume and resuming delivery of the first volume of fluid to the destination.

10 49. A system for simultaneously delivering a target volume of fluid from two sources in a desired ratio to a common destination, the system comprising:

a first fluid source;

a second fluid source;

15 fluid delivery means for delivering a first volume of fluid from the first fluid source and a second volume of fluid from the second fluid source to the destination in one or more first incremental volumes, the first incremental volume being substantially less than the target volume;

measuring means for measuring the volume of fluid delivered to the destination from the first source and the volume of fluid delivered to the destination from the second source; and

control means for suspending delivery of the first volume of fluid to the destination when the first volume exceeds the second volume by a predetermined fraction of the first incremental volume and resuming delivery of the first volume of fluid to the destination.

25 50. A system according to claim 49, wherein the desired ratio is 1:1.

51. A system according to claim 50, wherein the predetermined fraction is approximately one half.

01062/D54WO 247459.1

1/5

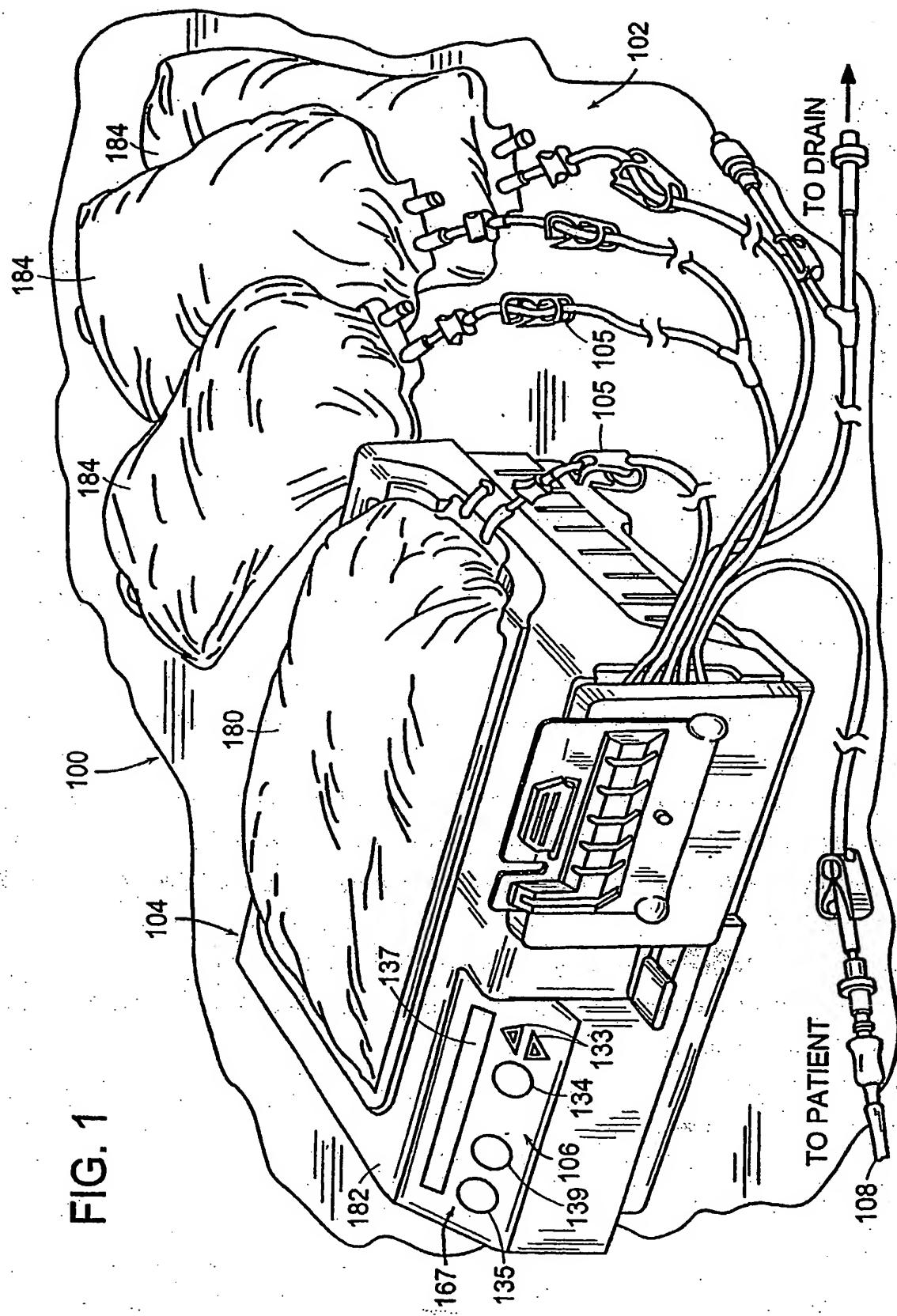


FIG. 1

SUBSTITUTE SHEET (RULE 26)

2/5

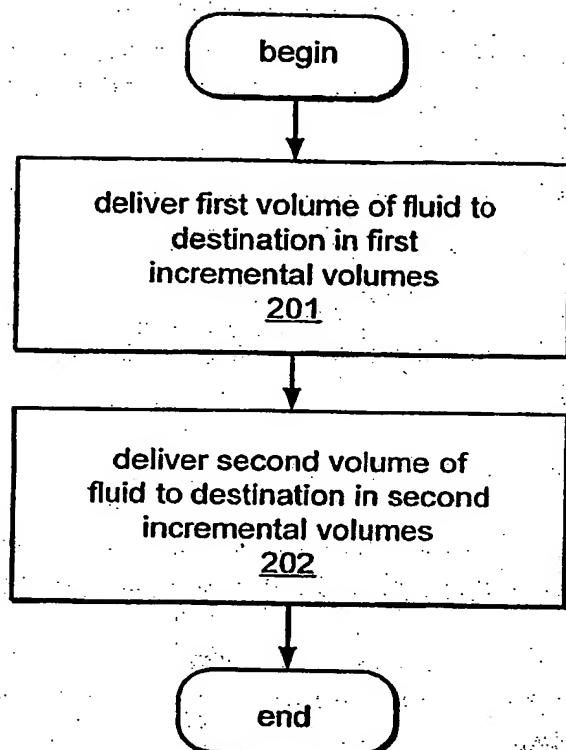


FIG. 2

3/5

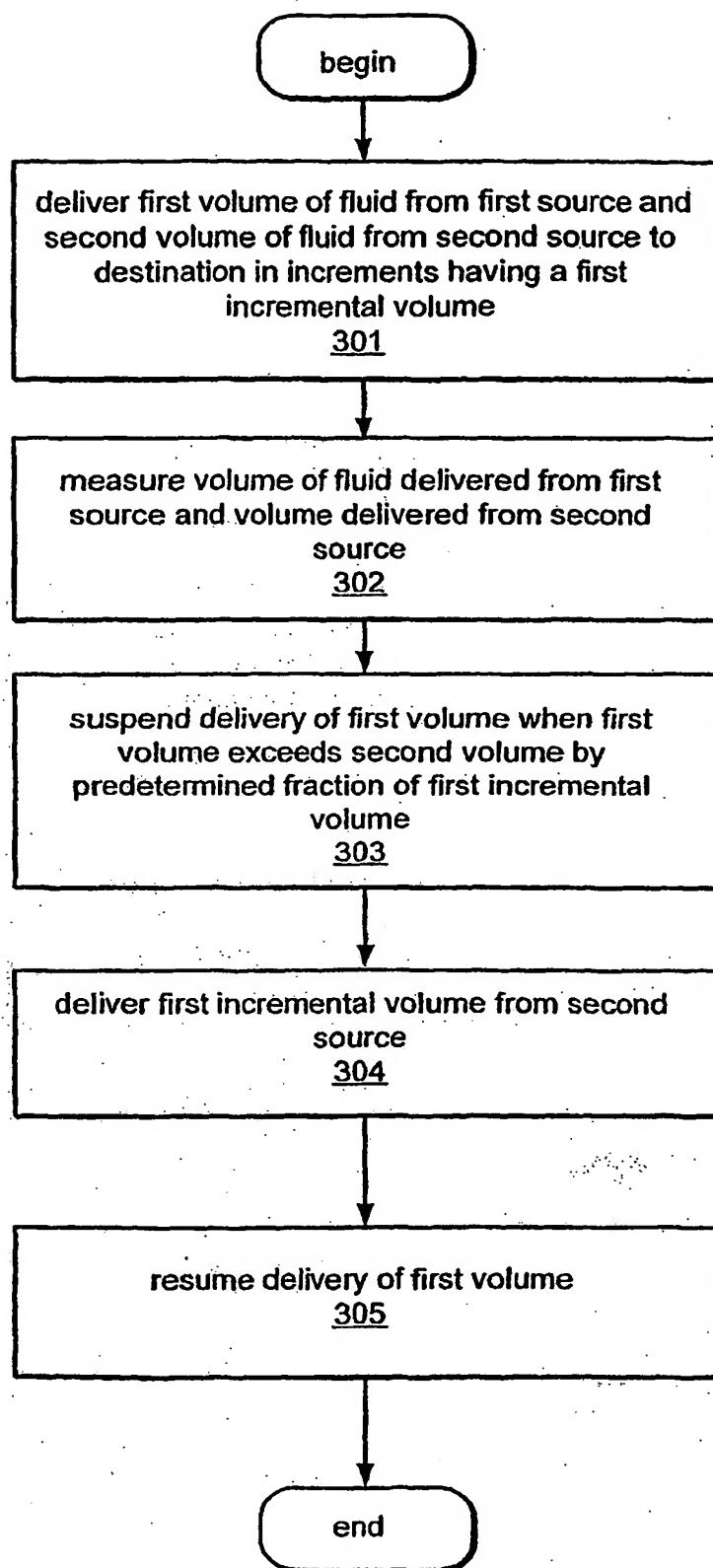


FIG. 3

4/5

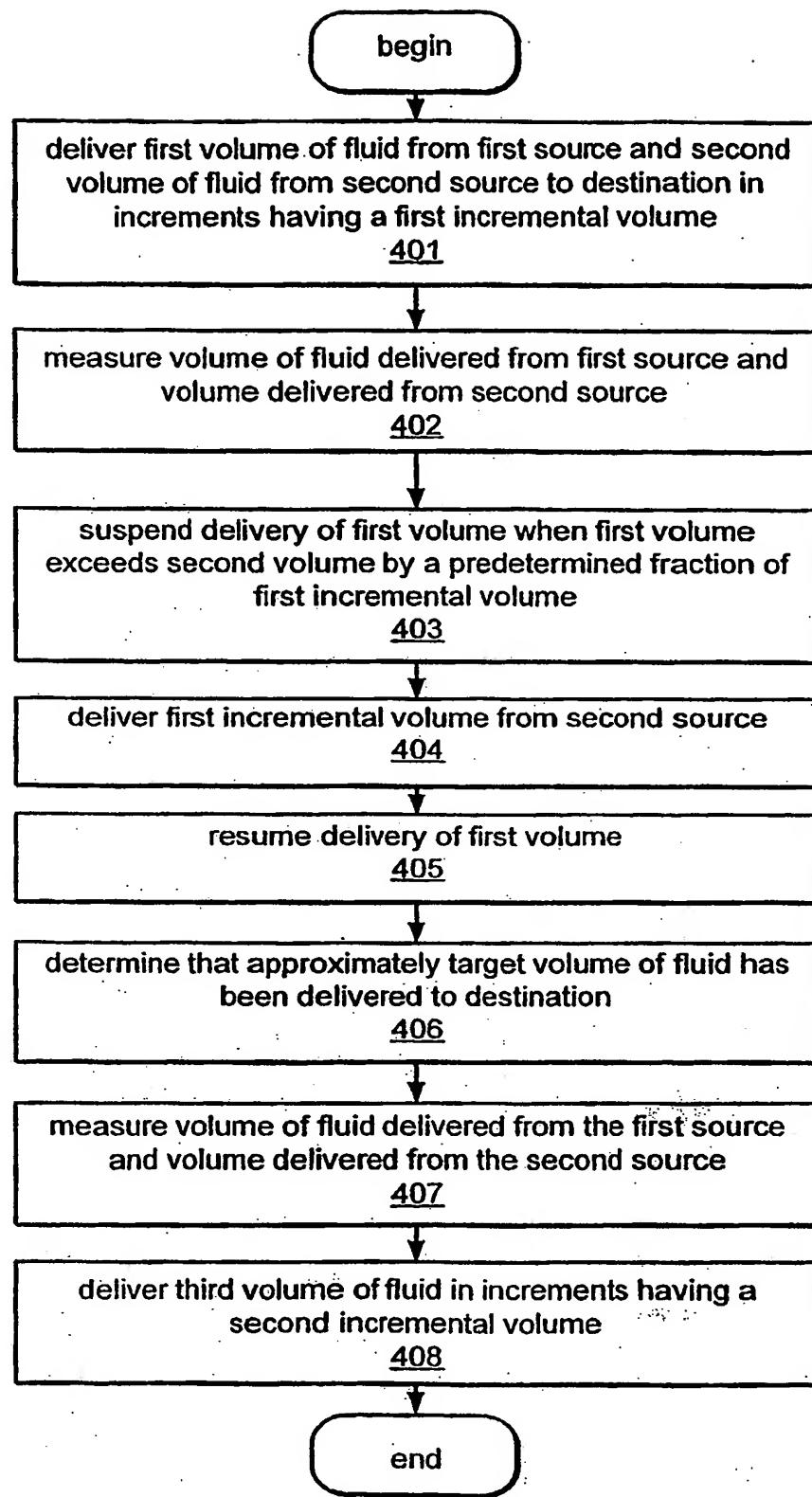


FIG. 4

5/5

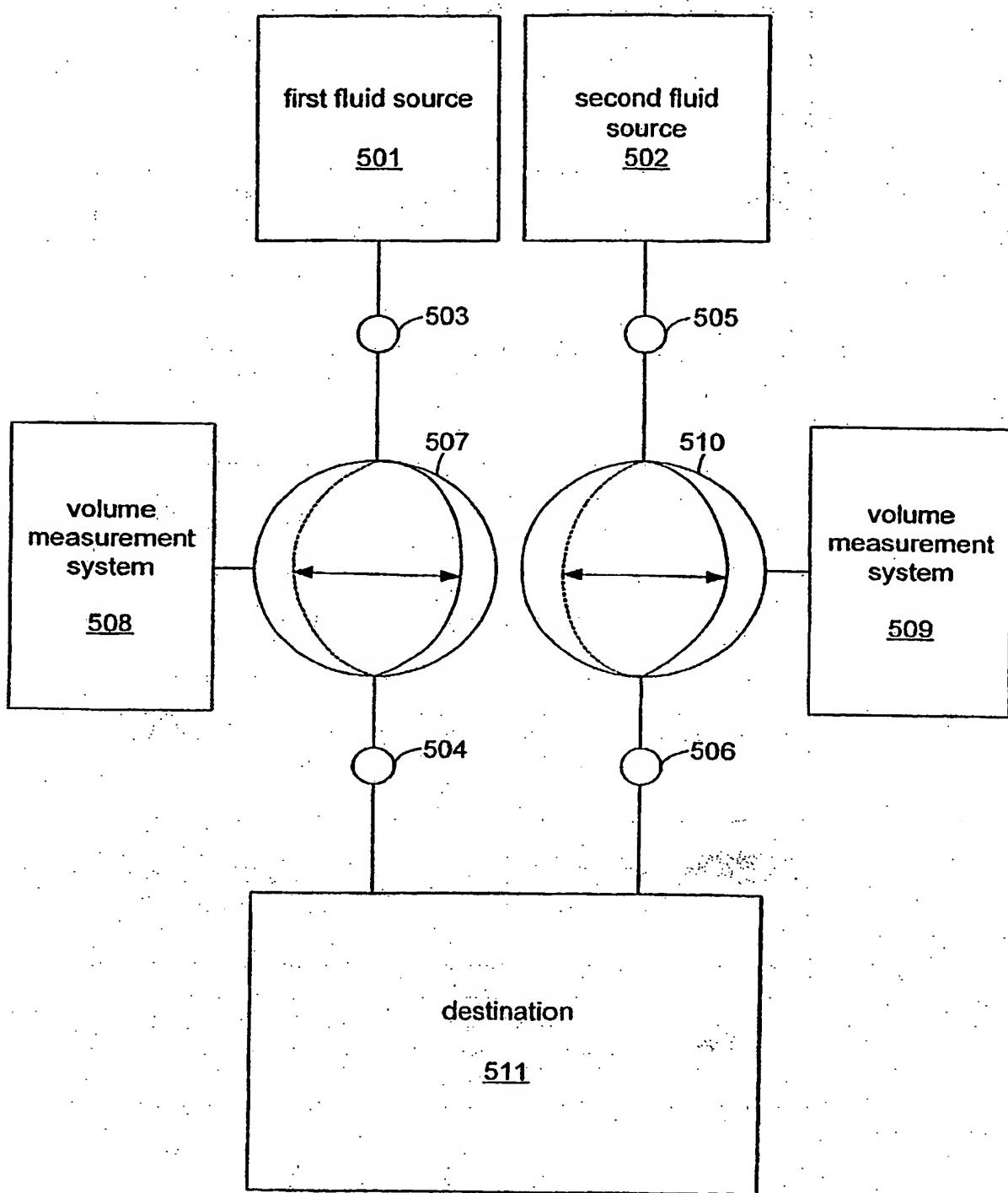


FIG. 5

SUBSTITUTE SHEET (RULE 26)

INTERNATIONAL SEARCH REPORT

Internat Application No
PCT/US 03/11090

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M5/168 A61M1/28

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 989 423 A (VINCENT DOUGLAS E ET AL) 23 November 1999 (1999-11-23) cited in the application abstract column 5, line 44 -column 6, line 36; figure 1 column 30, line 1 -column 31, line 19	10, 13-19, 33-36, 39-51
A	US 4 705 506 A (ARCHIBALD G KENT) 10 November 1987 (1987-11-10) the whole document	10, 13-19, 33-36, 39-51

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the International filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the International filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *Z* document member of the same patent family

Date of the actual completion of the International search

3 September 2003

Date of mailing of the International search report

12/09/2003

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel: (+31-70) 340-2040, Tx. 31 651 epo nl
Fax: (+31-70) 340-3016

Authorized officer

Nielsen, M

INTERNATIONAL SEARCH REPORT

Internal	Application No
PCT/US 03/11090	

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 013 334 A (DOEHN MANFRED DR) 23 July 1980 (1980-07-23) the whole document ---	10, 13-19, 33-36, 39-51
A	US 5 507 412 A (EBERT HOLGER ET AL) 16 April 1996 (1996-04-16) abstract ---	10, 13-19, 33-36, 39-51
A	US 4 966 579 A (POLASCHEGG HANS-DIETRICH) 30 October 1990 (1990-10-30) abstract ---	10, 13-19, 33-36, 39-51

INTERNATIONAL SEARCH REPORT

Int'l. application No.
PCT/US 03/11090

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 1-9, 11, 12, 20-32, 37, 38 because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT – Method for treatment of the human or animal body by therapy
2. Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
- No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Internal Ref.	Application No
PCT/US 03/11090	

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US 5989423	A 23-11-1999	US 5628908 A		13-05-1997
		AT 170759 T		15-09-1998
		AT 204770 T		15-09-2001
		BR 9404317 A		15-06-1999
		CA 2134204 A1		15-09-1994
		DE 69413166 D1		15-10-1998
		DE 69413166 T2		12-05-1999
		DE 69428138 D1		04-10-2001
		DE 69428138 T2		02-05-2002
		DK 643591 T3		07-06-1999
		DK 847769 T3		08-10-2001
		EP 0643591 A1		22-03-1995
		EP 0847769 A2		17-06-1998
		ES 2123770 T3		16-01-1999
		WO 9420154 A1		15-09-1999
		JP 3113886 B2		04-12-2000
		JP 7506518 T		20-07-1995
US 4705506	A 10-11-1987	US 4673390 A		16-06-1987
		CA 1266809 A1		20-03-1990
		EP 0223548 A2		27-05-1987
		JP 62114562 A		26-05-1987
		AU 574864 B2		14-07-1988
		AU 5000685 A		05-06-1986
		CA 1238542 A1		28-06-1988
		DE 3581610 D1		07-03-1991
		EP 0184918 A2		18-06-1986
		ES 290330 U		01-08-1986
		JP 61131754 A		19-06-1986
		KR 9200437 B1		14-01-1992
EP 0013334	A 23-07-1980	DE 2855713 A1		26-06-1980
		DK 539479 A		23-06-1980
		EP 0013334 A2		23-07-1980
		FI 794002 A		23-06-1980
		JP 55088768 A		04-07-1980
		NO 794057 A , B,		24-06-1980
US 5507412	A 16-04-1996	DE 4320365 A1		22-12-1994
		DE 9321077 U1		14-12-1995
		EP 0633035 A1		11-01-1995
		JP 7031865 A		03-02-1995
US 4966579	A 30-10-1990	DE 3817411 A1		30-11-1989
		DE 58904831 D1		05-08-1993
		EP 0343501 A2		29-11-1989
		ES 2045251 T3		16-01-1994

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- BLACK BORDERS**
- IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- FADED TEXT OR DRAWING**
- BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- SKEWED/SLANTED IMAGES**
- COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- GRAY SCALE DOCUMENTS**
- LINES OR MARKS ON ORIGINAL DOCUMENT**
- REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.